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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/539,562 | 06/17/2005 | Kristopher Buchanan | 09138.0070 | 2677 |
| 63432 7590 03/03/2009 DAKO/FINNEGAN, HENDERSON, LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413 | | | | |
| EXAMINER | | | | |
| BOWERS, NATHAN ANDREW | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1797 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 03/03/2009 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/539,562

Applicant(s)

BUCHANAN ET AL.

Examiner

NATHAN A. BOWERS

Art Unit

1797

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 75 and 90-121 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 75 and 90-121 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05 January 2009 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- 1) Claims 75 and 90-101 are rejected under 35 U.S.C. 102(b) as being anticipated by Richards (US 6296809).

With respect to claim 75, Richards discloses an automated sample processing system for processing a plurality of samples each on a respective carrier according to a processing protocol. Specifically, Richards indicates that samples are positioned on slides, which are in turn positioned on a carrier retention device in the form of a carousel (Figure 4:28). This is disclosed in column 6, lines 12-43. Column 6, lines 44-65 teaches that an active temperature regulation element comprising a resistive heaters,

temperature sensors and a microprocessor controller is also provided to monitor the temperature of each sample slide during processing. Figure 9 indicates that each slide (37) is positioned just above a heating element (64) and a temperature sensor (68). This is further described in column 9, lines 4-66. Since each slide (37) is independently and removably mounted over a different thermal platform (50) on upwardly depending posts (82), it is understood that each slide may be inserted or removed during the processing protocol without interrupting a processing of another sample.

With respect to claims 90-95, Richards discloses the system in claim 75 wherein the processing system is capable of executing a variety of different techniques. Column 1, lines 18-47 and column 4, lines 5-15 state that the system can operate as either an automated immunohistochemistry processing system or a fluorescent in-situ hybridization processing system. Column 3, lines 29-40 state that the apparatus is designed to accommodate DNA probe and/or antibody based staining procedures.

With respect to claims 96-98, Richards discloses the system in claim 95 wherein an active temperature reduction element is additionally provided. In column 7, lines 1-10 and column 14, lines 51-62, Richards teaches that cooling of the slide is accomplished through the use of Peltier coolers and fans.

With respect to claims 99-101, Richards discloses the system in claim 95 wherein the active temperature regulation element comprises a temperature ramp up and ramp down element, thus inducing regulated temperature increases and decreases within the sample. This is described in column 6, lines 44-65, column 9, lines 4-66, column 18, line 57 to column 19, line 28, and generally throughout the reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2) Claims 102-113, 116-118, 120 and 121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richards (US 6296809) in view of Ammann (US 20050233370).

With respect to claims 102-108, Richards discloses the system set forth in the rejections above. Richards discloses at least one container having a reagent therein, as well as a sample carrier retention device. Sample temperature control elements are provided for regulating the temperature of the contents of the sample carrier retention device. Richards, however, does not expressly disclose that reagent temperature control elements are provided for regulating the temperature of reagents before they are applied to the sample.

Ammann discloses an automated system for processing a plurality of reaction receptacles each capable of holding and transporting a sample. Reaction receptacles are transported to an arrangement of incubators (Figure 4:600,602,604,606) where they are maintained at a predetermined temperature. Paragraphs [0130], [0332] and [0337]-[0369] state that reagents are stored in separate containers located within a reagent cooling bay (Figures 35-39). Ammann teaches that thermoelectric modules and fan units provide the desired cooling capacity, and are capable of regulating the temperature of a plurality of reagents maintained in a plurality of containers.

Richards and Ammann are analogous art because they are from the same field of endeavor regarding automated sample processing systems.

At the time of the invention, it would have been obvious to equip Richard's reagent storage containers with cooling elements and a control system capable of

regulating the temperature within the reagent storage containers. Reagents typical of microarray processing systems are known in the art to be temperature sensitive and susceptible to degradation if maintained under undesirable conditions. As evidenced by Ammann, it is well known in the art to keep reagents at cool temperatures during storage to ensure that they do not prematurely expire.

With respect to claims 109-113, Richards and Ammann disclose the apparatus set forth in claim 102 as set forth in the 35 U.S.C. 103 rejections above. In addition, Richards clearly indicates that a sample temperature control element is provided to ramp up and ramp down the temperature of the sample maintained within the carousel retention device during processing. This has been described in the rejections above.

With respect to claims 116 and 117, Richards and Ammann disclose the apparatus set forth in claim 102 as set forth in the 35 U.S.C. 103 rejections above. Richards additionally describes the use of a rinse buffer in column 14, line 7. Ammann also discloses rinsing and washing steps throughout the reference. As described above, Ammann further teaches that thermoelectric modules and fan units are capable of regulating the temperature of a plurality of reagents maintained in a plurality of containers.

With respect to claims 118, 120 and 121, Richards and Ammann disclose the apparatus set forth in the 35 U.S.C. 103 rejections above. As previously noted with

regard to Richards, it is understood that since each slide (37) is independently and removably mounted over a different thermal platform (50) on upwardly depending posts (82), each slide may be inserted or removed during the processing protocol without interrupting a processing of another sample. Richards further discloses the use of a reagent carousel capable of adding fluids to various slides without interrupting the processing of other samples.

3) Claims 75 and 90-101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richards (US 6296809) in view of Kalra (US 6495106).

As described above, it is understood that the Richards apparatus is fully capable of inserting/removing a single slide during processing without interrupting the processing of other samples. However, in order to expedite prosecution, the Kalra reference has been provided as evidence that it is known in the art to insert/remove a sample carrier during processing without interrupting the processing of other samples.

Kalra discloses an automated system in which a dispensing head (Figure 4:70) is used to add various reagents to a plurality of sample slides (Figure 1:190) according to a predetermined protocol. Column 17, lines 54-61 state that slides can be removed from the system without interrupting the processing of remaining slides.

Richards and Kalra are analogous art because they are from the same field of endeavor regarding automated sample processing systems.

At the time of the invention, it would have been obvious to ensure that the Richards apparatus is capable of inserting or removing a single slide without interfering

with the processing of other slides. Kalra teaches in column 17, lines 54-61 that this is beneficial because it allows one to continue slide processing continuously with a minimum of intervention by the user.

4) Claims 102-113, 116-118, 120 and 121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richards (US 6296809) in view of Ammann (US 20050233370) and Kalra (US 6495106).

As described above, it is understood that the Richards apparatus is fully capable of inserting/removing a single slide during processing without interrupting the processing of other samples. However, in order to expedite prosecution, the Kalra reference has been provided as evidence that it is known in the art to insert/remove a sample carrier during processing without interrupting the processing of other samples.

Kalra discloses an automated system in which a dispensing head (Figure 4:70) is used to add various reagents to a plurality of sample slides (Figure 1:190) according to a predetermined protocol. Column 17, lines 54-61 state that slides can be removed from the system without interrupting the processing of remaining slides.

Richards and Kalra are analogous art because they are from the same field of endeavor regarding automated sample processing systems.

At the time of the invention, it would have been obvious to ensure that the Richards apparatus is capable of inserting or removing a single slide without interfering with the processing of other slides. Kalra teaches in column 17, lines 54-61 that this is

beneficial because it allows one to continue slide processing continuously with a minimum of intervention by the user.

5) Claim 114 is rejected under 35 U.S.C. 103(a) as being unpatentable over Richards (US 6296809) in view of Kalra (US 6495106) as applied to claim 75, and further in view of Gonska (US 6568770).

Richards and Kalra discloses the apparatus set forth in claim 75 as set forth in the 35 U.S.C. 103 rejections above. Richards, however, does not expressly state that a drawer is provided for housing the carriers.

Gonska discloses an automated system for handling various biological sample carriers (Figure 1:5). A plurality of drawers (Figure 2:9) are provided for storing the sample carriers in a controlled environment. This is disclosed in column 3, lines 41-65. Various samples and/or reagents are stored in the plurality of drawers until needed at a later time.

Richards and Gonska are analogous art because they are from the same field of endeavor regarding automated sample processing systems.

At the time of the invention, it would have been obvious to provide the Richards device with a drawer capable of holding slides and/or reagents until the commencement of processing. As evidenced by Gonska, storage drawers are well known in the art and considered to be effective means by which to hold processing materials for a predetermined period of time. The use of storage drawers in the Richards device would be accomplished in a predictable manner and would yield predictable results.

6) Claims 115 and 119 rejected under 35 U.S.C. 103(a) as being unpatentable over Richards (US 6296809) in view of Ammann (US 20050233370) and Kalra (US 6495106) as applied to claims 102 and 118, and further in view of Gonska (US 6568770).

Richards, Ammann and Kalra discloses the apparatus set forth in claims 102 and 118 as set forth in the 35 U.S.C. 103 rejections above. Richards, however, does not expressly state that a drawer is provided for housing the carriers.

Gonska discloses an automated system for handling various biological sample carriers (Figure 1:5). A plurality of drawers (Figure 2:9) are provided for storing the sample carriers in a controlled environment. This is disclosed in column 3, lines 41-65. Various samples and/or reagents are stored in the plurality of drawers until needed at a later time.

Richards and Gonska are analogous art because they are from the same field of endeavor regarding automated sample processing systems.

At the time of the invention, it would have been obvious to provide the Richards device with a drawer capable of holding slides and/or reagents until the commencement of processing. As evidenced by Gonska, storage drawers are well known in the art and considered to be effective means by which to hold processing materials for a predetermined period of time. The use of storage drawers in the Richards device would be accomplished in a predictable manner and would yield predictable results.

Response to Arguments

Applicant's arguments filed 08 December 2008 with regard to the 35 U.S.C. 102 rejections involving Richards have been fully considered but they are not persuasive.

Applicant's principle arguments are

(a) Richards does not disclose an automated sample processing system "wherein a carrier may be inserted or removed during a processing protocol without interrupting a processing of another sample."

In response, please consider the following remarks.

It is agreed that Richards does not expressly teach that sample slides are inserted or removed during processing without interrupting the processing of other samples. Richards is largely silent on the matter. However, as noted in the rejections above, the Richards apparatus is considered to be fully capable of being operated in this way. Since each slide (37) is independently and removably mounted over a different thermal platform (50) on upwardly depending posts (82), it is understood that each slide may be inserted or removed during the processing protocol without interrupting a processing of another sample. Each slide is heated by a separate heater, and therefore, the heating protocol of one slide will not be affected by the physical manipulation of neighboring slides.

Please also note the new rejections involving the combination of Richards with Kalra.

Applicant's arguments filed 08 December 2008 with regard to the 35 U.S.C. 103 rejections involving Richards and Ammann have been fully considered but they are not persuasive.

Applicant's principle arguments are

(a) Ammann teaches away from providing a system in which a carrier can be inserted or removed during a processing protocol without interrupting a processing of another sample.

In response, please consider the following remarks.

The Ammann reference is not relied on for teachings regarding processing protocol because the Richards reference already discloses an effective system in which sample carriers are inserted into a processing position, washed, treated with reagents, incubated and removed. Richards already discloses an arrangement in which individual slides can be removed and/or added without disturbing neighboring slides. The Ammann reference is only relied on for teachings regarding the heating of reagent fluids prior to use in the processing system. It is well within the purview of one of ordinary skill in the art to selectively utilize individual aspects of the Ammann device (such as heated reagents) without importing every feature described by Ammann. This is especially true in the instant situation where the use of heated reagents bears little relationship to whether or not slides can be added or removed without disturbing the entire process.

Please also note the new rejections involving the combination of Richards with Ammann and Kalra.

Conclusion

This is a non-final rejection.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHAN A. BOWERS whose telephone number is (571)272-8613. The examiner can normally be reached on Monday-Friday 7 AM to 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/
Primary Examiner, Art Unit 1797

/Nathan A Bowers/
Examiner, Art Unit 1797